K112705

Aalto Scientific, Ltd.

510(k) Notification
Audit® MicroLQ™ Serum Protein Control

JAN 2 4 2012

510(k) Summary

A. Submitter

Aalto Scientific, Ltd.
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Carlsbad, CA 92008
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B. Contact Person

Dessi Lyakov
Regulatory Affairs Manager
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C. Date of Summary Preparation

January 11, 2012

D. Device Identification

Product Trade Name:	Audit® MicroLQ™ Serum Protein Control
Common Name:	Serum Protein Control
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

Device to Which Substantial Equivalence is Claimed:

Product Trade Name:	Audit® MicroCV™ Protein Linearity Set Aalto Scientific, Ltd., Carlsbad, CA K101216

E. Description of the Device

The Audit® MicroLQ™ Serum Protein Control is a human based, liquid set of QC material. Each level of the set contains Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin analytes. It is used to confirm the proper calibration of Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin.

F. Statement of Intended Use

Audit® MicroLQ™ Serum Protein Control is an assayed, ready-to-use liquid, bi-level, human serum -based control for use with assays designed to quantitate: Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin. It is intended to simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin assays. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the Beckman Immage 800

The Audit® MicroLQ™ Serum Protein Control is for In Vitro Diagnostic use only.

G. Summary of Performance Data

Stability studies have been performed to determine the shelf life for the Audit® MicroLQ™ Serum Protein Control Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Shelf Life: Three years, when stored unopened at 2 - 8° C.

Note: Real time studies are ongoing to support the shelf life of this product.

H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit® MicroLQ™ Serum Protein Control Set (K112705)	Audit™ MicroCV™ Propein Linearity Set (K101216)
Intended Use	Audit® MicroLQ™ Serum Protein Control is an assayed, ready-to-use liquid, bi-level, human serum -based control for use with assays designed to quantitate: Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin. It is intended to simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin assays. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the Beckman Immage 800 The Audit® MicroLQ™ Serum Protein Control is for In Vitro Diagnostic use only.	The Audit™ MicroCV™ Protein Linearity is assayed quality control material consisting of five levels protein (human) based serum. Each level contains Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin analytes. The five levels demonstrate a linear relationship to each other for Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M, and Transferrin analytes. It is intended to simulate human patient serum samples and to detect systematic analytical deviations of laboratory testing procedures for Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M, and Transferrin. The product is intended for use with quantitativ assays on the indicated analyzer provided in the labeling. The Audit MicroCV Protein Linearity Set is "For In Vitro Diagnostic Use Only."
Number of Analytes per vial	16	7
Contents	6 x 2 mL	5 x 2 mL
Matrix	Human Based Serum	Human Based Serum
Type of Analytes	Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin.	Alpha-1-Antitrypsin, Complement C3, Complement C4, Immunoglobulin G, Immunoglobulin A, Immunoglobulin M and Transferrin
Form	Liquid	Liquid
Storage	2 to 8° C Until expiration date	2 to 8° C Until expiration date
Open Bottle Stability	36 months at 2 to 8° C	24 hours at 2 to 8°

I. Conclusions

Based upon the purpose of the device and the descriptions of the predicate device, the safety and efficacy, and the stability data generated, the product is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Aalto Scientific, Ltd.
c/o Dessi Lyakov
Manager, Regulatory Affairs
1959 Kellogg Avenue
Carlsbad, CA 92008

JAN 2 4 2012

Re: k112705
Trade/Device Name: Audit® MicroLQ™ Serum Protein Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: I
Product Code: JJY
Dated: November 22, 2011
Received: November 23, 2011

Dear Ms. Lyakov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Reena Philip

for Maria M. Chan, Ph.D.
Director, Division of Immunology and Hematology
Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Notification
Audit® MicroLQ™ Serum Protein Control

Indications for Use

510(k) Number: K112705

Device Name: AUDIT® MicroLQ™ Serum Protein Control

Indications For Use:
Audit® MicroLQ™ Serum Protein Control is an assayed, ready-to-use liquid, bi-level, human serum -based control for use with assays designed to quantitate: Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin. It is intended to simulate human patient samples for the purpose of monitoring the precision of laboratory testing procedures for Immunoglobulin E (IgE), Immunoglobulin M (IgM), Immunoglobulin G (IgG), Immunoglobulin A (IgA), Prealbumin, Antithrombin III, Alpha-1-Antitrypsin (AAT), Albumin, Complement C4 (C4), Complement C3 (C3), alpha-2-Macroglobulin, Alpha-1-Acid Glycoprotein, Ceruloplasmin, Transferrin, Haptoglobin, and Beta-2-Microglobulin assays. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on the Beckman Immage 800.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off Office of In Vitro
Diagnostic Device Evaluation and Safety

510(k) K112705